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Writer: David/Artist: Susan
Approval: Chris Donohue, Ellen Merlo
Legal: Marc Firestone, *R. Shidell*

NEW YORK—Philip Morris Inc. has joined four other U.S. cigarette manufacturers and an advertising agency in filing suit against the Food and Drug Administration and Commissioner David Kessler.

The suit asks the court to prevent the FDA from taking any action to regulate cigarettes, charging that the agency does not have statutory authority to regulate the product. (See related editorial, p. 8.)

The suit, filed August 10 in U.S. District Court in North Carolina, also asks the court to order the withdrawal of proposed FDA regulations because they are illegal.

The suit was filed following the release by Kessler of proposed regulations governing cigarettes. Shortly after Kessler's announcement, President Clinton said that he was using "executive authority" to implement the proposed FDA regulations.

The FDA is asserting jurisdiction over cigarettes under a federal law that gives the agency power to regulate medicines, medical devices and pharmaceutical products. The FDA claims that the nicotine in cigarettes is a drug and cigarettes themselves are "medical devices."

In their suit, the plaintiffs contend that the action by the FDA "is an unprecedented and unlawful effort to extend its regulatory reach far beyond its statutory mandate and usurp the authority of Congress."

The suit further contends that, since cigarette manufacturers make no claim that their products have any therapeutic value, the FDA cannot lawfully assert jurisdiction.

In addition, the suit maintains that the FDA action violates the First and Fifth amendments (freedom of speech and due process, respectively) to the U.S. Constitution and the federal Cigarette Labeling and Advertising Act.

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PM USA is being joined in the suit by Brown & Williamson Tobacco Corp.; Coyne-Beahm Inc.; Liggett Group Inc.; Lorillard Tobacco Co.; and Reynolds Tobacco Co.

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Critics charge that the FDA's action defies Congressional intent, as well as previous FDA declarations that the agency has no jurisdiction over tobacco products. A broad spectrum of observers have also questioned the First Amendment implications of the FDA's advertising and marketing-related proposals.

The far-reaching FDA proposals include:

- Banning tobacco vending machines.
- Prohibiting billboard advertising within 1,000 feet of schools or playgrounds and restricting tobacco ads on billboards and point-of-purchase material to black and white, text-only ads. Direct-mail ads would be similarly limited, as would ads in magazines that count 15% or more of their readers as minors.
- Prohibiting tobacco brand sponsorship of events.
- Prohibiting virtually all continuity promotions, such as Marlboro Country Store, in which consumers exchange proofs of purchase for merchandise.
- Creating a national minimum sales age of 18 superseding comparable state laws. Retailers would be required to check photo ID cards for proof of age.
- Prohibiting sales of individual cigarettes and sales of packs containing less than 20 cigarettes.
- Requiring the tobacco industry to spend at least \$150 million a year to support an antismoking educational campaign.

A 90-day public comment period on the proposals began August 10.

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The FDA's action followed months of posturing on the issue by Kessler, who has made the politically expedient issue of cigarettes a centerpiece of his tenure as head of the agency.

Because Kessler had himself recently come under fire from a House committee looking into alleged abuse of power by the FDA, critics question the timing of the proposals. The agency has been under particular attack during Kessler's reign from critics who charge it is

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neglecting its core responsibility of approving new drugs and medical devices.

In his latest stab at the tobacco industry, Kessler seized the issue of youth smoking, maintaining that the FDA regulations are designed to prevent minors from smoking.

But critics, noting Kessler's long-standing hostility to the tobacco industry, charge he is using the issue as the wedge to pursue his ultimate goal—restrictions, or a ban, on the sale of cigarettes to adults.

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Speaking on behalf of the industry at an August 10 news conference, Steve Parrish, senior vice president, corporate affairs, Philip Morris Companies Inc., said, "David Kessler is trying to sneak through the back door because Congress has repeatedly slammed shut the front door on the issue of regulating cigarettes under the same law the FDA applies to products sold for therapeutic or medicinal purposes."

He added: "Kessler's action can only be described as a Trojan Horse, set forward under the guise of preventing youth smoking, a goal everyone shares. Make no mistake—the real hidden agenda here is prohibition."

Parrish said that a letter by Kessler dated February 25, 1994, indicates an ominous intent toward the industry, despite the commissioner's professed intention to address only the youth-smoking issue.

In the letter, Kessler said, "A strict application of these provisions could mean, ultimately, removal from the market of tobacco products containing nicotine at levels that cause of satisfy addiction. Only those tobacco products from which the nicotine has been removed or, possibly, tobacco products approved by FDA for nicotine-replacement therapy would then remain on the market."

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Parrish said that President Clinton's position against youth smoking was universally accepted, and that the government alone could not solve the problem.

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"But," he noted, "of all options available to deal with the issue of youth smoking, the [Clinton] Administration has approved a course of action that opens the door for unelected federal bureaucrats to radically restrict the right of adults to choose to smoke, and the right of cigarette companies to market and sell a product enjoyed by nearly 50 million Americans.

"The FDA is simply the wrong government entity with the wrong legal mandate, and years of congressional and court decisions say exactly that."

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Emphasizing the regulations under which the tobacco industry already operates, Parrish noted that nine federal agencies oversee various facets of the industry, each having been granted that right by Congress. Cigarettes are also heavily regulated at the state level.

Moreover, just two months ago, PM USA unveiled an aggressive initiative to prevent minors from having access to cigarettes. The plan, called Action Against Access, is made up of 10 elements designed to ensure that consumers can only purchase cigarettes in face-to-face transactions where proof of age can be checked.

PM USA also voluntarily discontinued sampling and is supporting state efforts to restrict vending sales and to require licensing of retailers who sell cigarettes.

In addition, PM USA has voluntarily added a notice to its cigarette packages that says, "Underage Sale Prohibited." By January, the notices will begin to show up on packs and cartons sold in the U.S.

In a statement issued August 10, PM USA said it would "fight just as vigorously for our alternative program, which combines state level regulation and enforcement with voluntary efforts to make a real impact on this critical social issue."

But having opted to pursue more federal regulation, the Administration "has ensured that the more effective and expedient course of cooperative action takes second place to those who want to expand the federal bureaucracy and its unwanted intrusion into the private lives of adult Americans," PM USA said.

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Reaction in Congress from opponents of the plan was swift and heated.

Just after the announcement of the FDA plan, Sen. Wendell Ford (D: Ky.) took the floor of the Senate, saying, "My farmers lost out to the zealots. The Administration has chosen litigation over compromise, delay over action. The President has chosen a press conference instead of a negotiating conference. He has chosen a process that reaches his goals later rather than sooner."

Other Democrats from tobacco-producing states joined Sen. Ford in denouncing the FDA action, while Republicans attacked the plan as another example of "big-government" meddling in the affairs of the American people.

Rep. Thomas Bliley (R: Va.), chairman of the Commerce Committee, said "the real tragedy is that by playing this gambit, [President Clinton] ignored countless current federal and state regulations over tobacco, and rejected far-reaching voluntary initiatives that would have produced significant reductions in teenage smoking in the meantime."

Observers expect members of Congress to introduce legislation this month seeking to overturn the FDA's move, when they return from summer recess. Rep. Lewis Payne (D: Va.) said he would introduce a bill barring the FDA from regulating the sale or use of tobacco or tobacco products.

In the Senate, Sen. Ford indicated he would introduce a bill designed to keep tobacco away from minors while avoiding FDA regulation.

Tobacco farmers and executives in affected industries—from vending machines to advertising—also joined the tobacco industry and politicians in criticizing the FDA plan.

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Many in the media panned the plan as well, on matters ranging from abuse of power to the ill-fated nature of such efforts by the federal government to the danger it posed to First Amendment freedoms.

In *Advertising Age*, one writer attacked the "abridgments of speech" in the FDA proposals related to cigarette marketing, saying President

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Clinton "is sidestepping the First Amendment as if it were a puddle in the street."

The New York Post, in urging the tobacco companies "to fight Clinton & Co.'s demagogic approach to this issue all the way to the Supreme Court," called the Administration's effort "an utterly inappropriate and punitive attack on a legal American business."

"Classifying nicotine as a drug—in order to let the Food and Drug Administration regulate cigarette sales—seems a clear prelude to an outright ban," wrote the Post. "Certainly, David Kessler... has indicated that he sympathizes with the health fascists who want to make cigarettes illegal."

The Orange County [Calif.] Register called the program "a massive increase in the power of the federal Food and Drug Administration, one of the most unaccountable, inefficient and virtually-immune-to-real-science agencies in the national government. The president is authorizing the FDA... to take over what has up to now been the responsibility of state governments."

"Does the cynical use of children to increase political power and seize assets constitute child abuse?" the newspaper asked.

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Meanwhile, in an August 10 letter to employees, Chairman and CEO Geoffrey Bible called the FDA action "an ill-disguised attempt to use the issue of youth smoking to ultimately ban all tobacco use by adults."

"We strongly agree that kids should not smoke," Bible wrote. "Philip Morris had demonstrated that belief over and over again, and reaffirmed it just recently when we launched Action Against Access.

"However, we are totally opposed to granting regulatory authority for tobacco to the FDA. We believe such a move is ill-advised, illegal, and an ill-disguised attempt to use the issue of youth smoking to ultimately ban all tobacco use by adults."

Bible said PM is "prepared to use all the resources at our disposal to fight as long and as hard as we must to preserve our right to manufacture and market—and our customers right to sell—our legal tobacco products to adults who choose to smoke."

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And, as in past battles, employees are pledging to make their voices heard (see box).

(NOTE: Waiting to get an employee quote from Richmond or Cabarrus to wrap up story.)

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